

JOHN GIORDANO
United States Attorney
DAVID V. SIMUNOVICH
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, NJ 07102
Tel.: (973) 645-2736
david.simunovich@usdoj.gov

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA *et al.*
ex rel. ATUL JAIN,

Plaintiffs,

v.

DIOPSYS, INC., *et al.*,

Defendants.

HON. ESTHER SALAS

Civil Action No. 21-18151 (ES) (LDW)

FILED EX PARTE & UNDER SEAL

**THE UNITED STATES' NOTICE OF ELECTION TO INTERVENE
IN PART FOR PURPOSES OF EFFECTUATING SETTLEMENT
AND TO DECLINE TO INTERVENE IN PART**

The United States, Relator Atul Jain, and Defendant Diopsys, Inc. (collectively with the United States and Relator, the “Settling Parties”), have reached a settlement agreement to resolve the claims brought on behalf of the United States in this action.¹ In light of this agreement, and for the purpose of

¹ In addition to bringing this action on behalf of the United States under the federal False Claims Act, Relator also brought suit on behalf of the States of California, Texas, Florida, Ohio, North Carolina, Oklahoma, New York, Hawaii, Maryland, and New Jersey (collectively, the “Named States”). This notice of election does not cover claims that Relator has brought on behalf of the Named States. However, the Named States do not object to the relief sought in this notice and the accompanying proposed order. We understand that the Named States, Relator and

effectuating and formalizing that resolution, pursuant to the False Claims Act, 31 U.S.C. §§ 3730(b)(2) and (4), the United States respectfully advises the Court of its decision to intervene in part for the purpose of effectuating the settlement agreement, and to decline to intervene in part as to all remaining allegations in this case.

Specifically, the United States intervenes in this action with respect to civil claims under the federal False Claims Act against Diopsys predicated upon the following factual allegations (the “Covered Conduct”):

The United States contends that it has certain civil claims against Diopsys arising from Diopsys’s marketing of the NOVA system during the period from January 1, 2015 through March 1, 2022. Specifically, on or about May 9, 2011, Diopsys obtained FDA 510(k) clearance of its NOVA medical device, an electrophysiological device that ophthalmologists could use to conduct visual evoked potential (VEP) testing. By June 2012, Diopsys had made substantial changes to the NOVA device, enabling it to conduct electroretinography (ERG) testing, but Diopsys did not seek further clearance from FDA for the changes to the NOVA device despite knowing that VEP and ERG testing were substantially different tests and that FDA had not cleared the NOVA device with the ERG component. Over time, Diopsys added three different types of ERG tests to the device (full-field ERG, pattern ERG, and multi-focal ERG). Diopsys sales representatives promoted the ERG features of NOVA as “completely new” and advised customers on how to maximize reimbursement for tests conducted using the device. Internal Diopsys records referred to “new” electrodes being added to the device to conduct ERG testing, along with a “new manufacturing process.” Diopsys knew, or was reckless in not knowing, that the changes to the NOVA device were substantial and

Diopsys have also reached an agreement in principle and anticipate executing a civil settlement agreement similar to that reached between the United States, Relator, and Diopsys.

required submission to the FDA for clearance or approval. Diopsys sales personnel described how doctors could maximize their financial return on NOVA and further marketed NOVA for medically unnecessary uses causing physicians to submit false claims to federal and state health care programs.

Under the terms of the agreement among the Settling Parties, following Diopsys's first installment payment, the United States and the Relator will file a Notice of Voluntary Dismissal to (i) dismiss with prejudice Relator's claims against Diopsys and (ii) dismiss with prejudice the United States' claims as to the Covered Conduct as to Diopsys and without prejudice as to any other claims.

In light of the agreement reached among the Settling Parties, the United States does not presently intend to file a complaint in intervention as against Diopsys, but reserves the right to seek leave to file such a complaint in the event that Diopsys does not pay the full settlement amount consistent with the terms of the settlement agreement.

The United States declines to intervene with respect to any claims asserted by Relator against defendants other than Diopsys. Although the United States declines to intervene in a portion of the action, we respectfully refer the Court to 31 U.S.C. § 3730(b)(1), which allows the Relator to maintain the declined portion of the action in the name of the United States; providing, however, that the "action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." *Id.* Therefore, the United States requests that, should either the Relator or any of the remaining Defendants propose that the part of the action in which the United States has not intervened be

dismissed, settled, or otherwise discontinued, this Court solicit the written consent of the United States before ruling or granting its approval.

Furthermore, pursuant to 31 U.S.C. § 3730(c)(3), the United States requests that all pleadings filed in this action, even as to the non-intervened part of this action, be served upon the United States; the United States also requests that all orders issued by the Court be sent to the Government's counsel. The United States reserves its right to order any deposition transcripts and to intervene in the portion of this action in which it is declining to intervene today, for good cause, at a later date.

The United States reserves the right to seek the dismissal of the relator's action or claim on any appropriate grounds, including under 31 U.S.C. §§ 3730(b)(5) and (e)(4).

Finally, the United States hereby requests that the Court unseal the Relator's Complaint, this Notice of Election, and all subsequent filings following this Notice of Election. The United States further requests that all other papers on file in this action remain under seal because in discussing the content and extent of the United States' investigation, such papers are provided by law to the Court alone for the sole purpose of evaluating whether the seal and the time for making an election to intervene should be extended.

A proposed order accompanies this Notice.

Dated: Newark, New Jersey
March 20, 2025

Respectfully submitted,

JOHN GIORDANO
United States Attorney

By: /s/ David V. Simunovich
DAVID V. SIMUNOVICH
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, NJ 07102
Tel. (973) 645-2736
david.simunovich@usdoj.gov